AY 2020-21 Onwards

Hindi Vidya Prachar Samiti's

RAMNIRANJAN JHUNJHUNWALA COLLEGE (AUTONOMOUS)

(Also known as R. J. College of Arts, Science & Commerce as per UGC Notification)

Affiliated to UNIVERSITY OF MUMBAI II Recognized by UGC under 2f & 12B
NAAC Accredited 'A GRADE' with CGPA 3.50

Knowledge is all Ambrosia

Postgraduate Diploma in

Regulatory Affairs

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Mumbai 400 086, Maharashtra, INDIA.

Post Graduate Diploma in Regulatory Affairs

Hindi Vidya Prachar Samiti's

Ramniranjan Jhunjhunwala College

Of Arts, Science & Commerce

(Autonomous College)

Affiliated to
UNIVERSITY OF MUMBAI

Syllabus for the Post Graduate Diploma

Program: Post Graduate Diploma in Regulatory Affairs

Program Code: RJSPGDRA

(Revised Syllabus Academic year 2020-2021)

Post Graduate Diploma in Regulatory Affairs

Program Code: RJSPGDRA

Preamble:

The post graduate Diploma in Regulatory Affairs is designed to produce trained manpower who are highly qualified to manage the regulatory process for companies innovating in new product developed. Regulatory affairs is a profession developed by the government to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicine. This program will help in training manpower to work in an ever-growing industry. There is a wide variety of careers in the regulatory affairs. Regulatory professionals can work as Regulatory affair specialist, manager, director, compliance specialist, food safety inspector, Director of quality assurance.

Post Graduate Diploma in Regulatory Affairs

Title: Post Graduate Diploma in Regulatory Affairs

Eligibility: B.Pharm, B.Sc (Botany, Zoology, Chemistry, Biochemsitry, Biotechnology, Microbiology, Life Sciences), PhD's and Pharmaceutical Professionals

Duration of the Course: One Year (Part- time) Blended teaching weekends

Fee Structure:

Tuition Fee	:	25,000.00
RFID	:	150.00
Examination Fees	:	500.00
Application form fees	:	Rs 100.00

Intake capacity: 40 students

Faculty: Drawn from Industry and Academia Proficient in areas of horticulture, Botany, plant propagation, consultant

Standard of Passing

a. Candidate who secures minimum 50% marks in each paper be declared to have passed the examination in that subject.

b. A candidate who fails to secure 50% marks in a paper will be allowed to reappear in that paper.

Post Graduate Diploma in Regulatory Affairs

c. Candidate can carry forward at his/her option the marks in the paper in which he/she has passed, in such a case student is entitled for award of class.

d. Candidate who secures a minimum of 50% marks in each paper and an aggregate of 60% and above marks on the whole shall be declared to have passed the examination in the First Class.

e. Candidate who secures a minimum of 50% marks in each paper and an aggregate of 70% and above marks on the whole shall be declared to have passed the examination in First Class with Distinction.

Medium of Instruction English

Scheme of evaluation:

There would be continuous evaluation with internal assessment of MCQ, quiz, presentation, assignment, 40% weightage,

External evaluation: Subjective with 60% weightage

Post Graduate Diploma in Regulatory Affairs

Semester	TITLE OF PAPER	MAXIMUM MARKS	MINIMUM MARKS	Credits	Course CODE
I	Regulatory Affairs-I	300	150	24 Credits	RJSPGDRA101
II	Regulatory Affairs-II	300	150	24 Credits	RJSPGDRA102
	Total	**600**	**300**	**48 Credits**	

Syllabus for Post Graduate Diploma in Regulatory Affairs

Important to Regulatory Affairs in Pharma Industry

- Basic regulatory framework with respect to Regulated and Non-regulated market practices and procedures.
- Global Pharmaceutical Industry Scenario.

Semester I RJSPGDRA101 **24 Credits**

Basic ICH Requirement

ICH Topics

Q1 -Stability

Q2 -Analytical Validation

Q3 –Impurities

Q4 –Pharmacopoeia

Q6 –Specifications

Q7 –GMP API

Q8 –Pharmaceutical Development

Q9 –Quality Risk Management

Q10 –Pharmaceutical Quality System

Q11 –Development and manufacture of drug

Regulatory Filing systems for Active Pharmaceutical Ingredients in different countries.

- EU - ASMF, CEP, EU DMF
- US – DMF application, preparation and annual report.
- Semiregulated Markets- Requirement of API.
- Genotoxic Impurities, Elemental Impurities, Polymorphic form and characterization.
- Various types of DMF

- CTD –Module 1,2,3
- Quality Overall Summary (QOS)
- Quality by design concept applicable to API
- Post approval changes and handling deficiencies

Regulatory Filing systems in Europe.

- EMEA Procedures –Centralized, Decentralized, Mutual recognition and National procedure.

- CTD-Module 1, 2, 3, 4, 5 (including QOS, quality design concept and bioequivalence).
- Variation and Renewals
- Query-Response.

Semester II RJSPGDRA201 **24 Credits**

Regulatory Filing systems in US.

- Various Types of application - IND, NDA and ANDA.
- CTD- Module1, 2, 3 and CTD Overall summary -Module1, 2, 3 including quality overall summary and Quality by design CTD module. Module 4 and 5 (including Bioequivalence).
- Post approval changes.

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Registration procedures in various countries:

- Australia
- New Zealand
- Canada
- South Africa/Africa
- Latum
- DCGI(India)
- Asia
- Russia/CIS

Pharmacovigilance in EU/US

- Interviews for Regulatory Opening.
- Case study for both US and EU

AUDIT Checklist

- Prior Approval Inspections (PAI)
- Out of Specifications (OOS), Inspection and Audits, Deviations and Change Controls
- Annual Product Reviews (APRs) for Pharmaceuticals

References:

- Stability Testing of New Drug Substances and Products Q1A(R2)
- Validation of Analytical Procedures: Text and Methodology Q2(R1)
- Impurities in new drug substance Q3A(R2)
- Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances (Q6A)
- Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (Q7)
- Organization of the Common Technical Document For the Registration of Pharmaceuticals for Human Use M4
- DISSOLUTION Guidance (USP pharmacopoeia Chapter 711)

Postgraduate Diploma in Regulatory Affairs

Sr. No	Roll No	Name of the Student	Grade	Certificate No
1	201	Sanghamitra .V. Gawai	A+	PGDRA-201920-01
2	204	Nutan Balkrishna Bavkar	O	PGDRA-201920-02
3	205	Gauri Bhave	O	PGDRA-201920-03
4	208	Sonali Ganjave	O	PGDRA-201920-04
5	209	Vrishali Gaonkar	O	PGDRA-201920-05
6	210	Jobin George	A+	PGDRA-201920-06
7	212	Saurabh Gurav	O	PGDRA-201920-07
8	213	PRANITA PRAMOD HULE	O	PGDRA-201920-08
9	215	Trupti Kavale	A+	PGDRA-201920-09
10	221	Poonam Patil	O	PGDRA-201920-10
11	222	Sagar Sudhakar Phad	O	PGDRA-201920-11
12	224	Mrunal Posam	O	PGDRA-201920-12
13	226	Nilesh Rane	A+	PGDRA-201920-13
14	227	MADHURA RANE	O	PGDRA-201920-14
15	233	YASH V. THANAWALA	O	PGDRA-201920-15
16	234	Sonali. G. Vadher	O	PGDRA-201920-16
17	235	Gauri Rajendra Vartak	O	PGDRA-201920-17
18	236	Chandini Yadav	A+	PGDRA-201920-18
19	239	Jigna .V.Gogri	O	PGDRA-201920-19
20	241	MANALI DILIP DESHMUKH	A+	PGDRA-201920-20
21	231	Manali M Shukla	A+	PGDRA-201920-21
22	229	Prajakta Prakash Sawant	O	PGDRA-201920-22
23	223	Siddhi Phadte	A+	PGDRA-201920-23
24	211	Janhavi S. Ghaisas	O	PGDRA-201920-24
25	220	Supriya Murkute	A	PGDRA-201920-25
26	228	PRAJAKTA RANE	O	PGDRA-201920-26

Hindi Vidya Prachar Samiti's

RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce (Autonomous)

Affiliated to UNIVERSITY OF MUMBAI

CERTIFICATE OF MERIT

This is to certify that

GHAISAS JANHAVI SHRIKANT SUNITI

has secured

"O"

in Postgraduate Diploma in Regulatory Affairs

in the examination held in Oct 2020.

Controller of Examination

Principal

Certificate ID: PGDRA-201920-24